PARTICIPANT INFORMATION SHEET

PARTICIPANT INFORMATION SHEET FOR A RESEARCH PROJECT (intended for type 2 diabetes mellitus patients invited to participate in the feasibility or effectiveness trial to evaluate an SMS-based intervention aimed at promoting adherence to antidiabetic medication and healthy lifestyle habits) (v0; August 13, 2020)

STUDY TITLE: Effectiveness study through a randomized clinical trial of an SMS-based intervention to promote adherence to antidiabetic medication and healthy lifestyle habits in type 2 diabetes mellitus patients

SPONSOR CODE: RTI2018-096935-A-I00

SPONSOR: Ministry of Science, Innovation, and Universities

PRINCIPAL INVESTIGATOR:

CENTER: Institut d'Investigació Sanitària Illes Balears

INTRODUCTION
We are contacting you regarding a study we would like to invite you to participate in. The study has been approved by the Research Ethics Committee of the Balearic Islands, in compliance with current legislation, and is conducted in accordance with the principles outlined in the Declaration of Helsinki and the rules of good clinical practice.

The purpose of this document is to provide you with the necessary information to decide whether you wish to participate in this study. Please read this information sheet carefully, and we will clarify any questions that may arise after the explanation. If you have any questions, please contact the principal investigator of the study.

GENERAL DESCRIPTION
This study aims to evaluate an SMS messaging service for individuals with type 2 diabetes, providing information on key aspects of diabetes care (medication intake, balanced diet, and physical exercise). This service will enable participants to receive free, personalized SMS messages on their mobile phones, offering useful information about their condition. Specifically, the SMS messages are designed to help address potential issues that may arise when taking antidiabetic medication and support individuals with diabetes in maintaining a healthy lifestyle through a balanced diet and physical activity.

In this study, your therapeutic compliance, physical activity level, and adherence to the Mediterranean diet will initially be evaluated to establish your profile. Additionally, we will ask for your consent to review the information available in your health history to personalize the messages according to your results and the medication you are currently taking. Based on this information, you will receive text messages on your mobile phone with information tailored to your needs over 12 months, with a maximum frequency of 5 messages per week.

Your participation in this study involves:

- Responding to an initial telephone interview (approximate duration: 60 min) to discuss

aspects related to your health and lifestyle.
- Reading the messages you receive on your mobile phone containing relevant information.
- Participating in an interview (individual or group*) after completing the study to better understand your impressions of the SMS service.

*If participating in a group interview, it will be video recorded to recognize participants' voices during the transcription of the collected material, which will be analyzed later by researchers.

WHAT PARTICIPATING IN THIS STUDY WOULD ENTAIL FOR ME

Your participation in this study would involve receiving text messages designed for patients with type 2 diabetes, aimed at helping you overcome difficulties you may face with medication intake, maintaining a balanced diet, and engaging in physical exercise, as well as other aspects related to disease management. The time commitment required for completing the initial interview and participating in the final focus group and/or individual interview will be approximately 2 hours in total. These text messages have been prepared by a team of healthcare professionals from IBSalut (doctors, nurses, psychologists, dietitians-nutritionists, and physiotherapists) in collaboration with diabetes patients. The text messages will be personalized based on information recorded in your health history, allowing us to send you information we believe may be most useful to you, such as recent blood sugar test results, information about upcoming appointments at the health center, anti-diabetic medication you are taking, or the most relevant information for you considering your various health issues (e.g., hypertension, high blood cholesterol, kidney disease, diabetic foot, eye examinations, overweight, sedentary lifestyle, smoking). Therefore, to participate in the study, access to certain data in your health history will be required.

BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY

Participation in this study will provide you with informative content on diabetes management that may be helpful for improving your health. Even if it does not, your help could contribute to designing a service that is as useful as possible for helping diabetes patients better cope with their disease.

Participation in this study does not involve any risks, as it only consists of receiving and reading a few text messages on your mobile phone and talking for about an hour about your personal characteristics, preferences, and opinions regarding the message service you received.

INFORMATION ON PERSONAL DATA PROTECTION

In compliance with Regulation (EU) 2016/679 (“GDPR”) and Organic Law 3/2018 on Personal Data Protection and guarantee of digital rights (“LOPDGDD”), the participant is informed about the processing of their personal data.

Purpose and legal basis of processing: your personal data will be processed for scientific research, studies, trials, programs, and educational activities, with the aim of developing health promotion functions, disease prevention, education, and as a complement to the necessary healthcare activity of the public healthcare centers, as well as for epidemiological research and similar activities. Your personal data will be processed by the Primary Care Management of Mallorca and incorporated into the “health research” treatment activity.

The processing of your personal data is based on the consent you provide for the purposes specified above, in the fulfillment of a mission carried out in the public interest or in the exercise of public powers conferred on the data controller, in compliance with a legal obligation applicable to the data controller, and to protect the vital interests of the data subject or another natural person.

Data Controller: Primary Care Management of Mallorca, located at Carrer de l'Escola Graduada, 3, 07002 Palma, Balearic Islands.

Personal data recipients: No communication of your personal data is foreseen.

Retention period of personal data: They will be kept for as long as necessary to fulfill the purpose for which they were collected and to determine any potential liabilities that may arise from that purpose and data processing.
Exercise of rights and claims: You have the right to withdraw your consent at any time, to object to the processing of your data, as well as to limit it, access, rectify, erase the data, and exercise your right to data portability, by submitting a written request addressed to the User Service of Primary Care of Mallorca, at Carrer de l'Escola Graduada, 3, 07002 Palma, Balearic Islands. The request to exercise any of your rights must be accompanied by a copy of an official document that identifies you (ID, driver's license, or passport). Lastly, we inform you that you may contact the Spanish Data Protection Agency and other competent public bodies for any complaint arising from the processing of your personal data.
Data Protection Delegate: The Data Protection Delegate of the Balearic Islands Health Service is located at Calle de la Reina Esclarmunda, 9, in Palma (Mallorca). Contact email: dpd@ibsalut.es

ECONOMIC COMPENSATION
Participation in this study does not involve any form of financial compensation. Possible travel expenses to the focus group location will not be reimbursed. None of the researchers will be remunerated based on your participation in the study.

VOLUNTARY PARTICIPATION
You should know that your participation in this study is voluntary and that you may decide not to participate or change your mind and withdraw your consent at any time without providing any explanation, and this will not affect your relationship with your health center or Primary Care Management.
To revoke your consent, you must contact the Principal Investigator. If you decide to withdraw your consent, no new data will be collected, nor will any further analysis of the sample be conducted, but this revocation will not affect the research conducted up to that point.

ACKNOWLEDGMENT
Regardless of your decision, both the sponsor and the research team would like to thank you for your time and attention. You are contributing to a better understanding and management of your disease, which may benefit many people in the future.